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Binaural Beat Technology: A Complementary Path to Post Deployment Wellness

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Program, 4301 Jones Bridge RD
Bethesda, MD 20814

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14. ABSTRACT

Purpose: To assess the efficacy of embedded theta brainwave frequency (4-7 Hz) in music using Binaural Beat Technology (BBT) compared to using music alone on the cardiovascular stress response in military service members with chronic stress following deployment.

Design: Double-blinded, randomized, pre and post-intervention trial

Methods: Participants were randomized to either Music with BBT or Music Alone groups. Each group listened to their intervention for a minimum of 30 minutes at bedtime for at least three consecutive nights per week, for four weeks. A 20-minute pre and post-intervention heartrate variability (HRV) stress test and daily perceived stress assessed intervention efficacy.

Sample: 74 service members with chronic stress following deployment.

Analysis: A 2 x 2 mixed ANOVA (between and within design).

Findings: There was a statistical difference (p = .01) in low frequency HRV between the music with BBT group compared to the music only group. The average low frequency HRV decreased 2.5 ms2/Hz using BBT, while using music alone increased 7.99 ms2/Hz. There was also a significant difference (p = .01) in the high frequency HRV measures, with BBT showing an increase by 2.5 ms2/Hz compared to music only, which decreased by 12.64 ms2/Hz. Significant (p = .01) differences were found in Total Power measures, with the music only group decreasing by 1113.64 ms2/Hz compared to 26.68 ms2/Hz in the BBT group. Daily diaries consistently showed that participants who used BBT reported less stress over the four weeks.

Implications for Military Nursing: BBT does not require a doctor's order or to be administered by an advanced practice provider. It can be an independent, nurse-initiated action at the bedside, in an outpatient setting, or on military deployments. BBT has the capacity to help other deployment health concerns, such as the beta frequency range to improve focus and the delta frequency range to improve sleep quality.

15. SUBJECT TERMS
Binaural Beat Technology, Wellness, ANOVA

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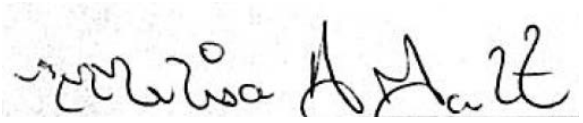
PI Signature  Date 10 March 2017

Mentor Signature  Date 6 March 2017

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Abstract

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TSNRP Research Priorities that Study or Project Addresses

Primary Priority

Force Health Protection:	☒ Fit and ready force ☐ Deploy with and care for the warrior ☐ Care for all entrusted to our care
Nursing Competencies and Practice:	☐ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☐

Progress Towards Achievement of Specific Aims of the Study or Project

Research Question: What is the efficacy and feasibility of implementing a Binaural Beat Technology (BBT) intervention in a military population during the high-risk post-deployment window?

Aim 1 - To assess the impact of BBT on anxiety and stress relevant cardiovascular health measures by:
a. Comparing pre and post intervention state anxiety scores
b. Observing the trend of morning blood pressure surge over time
c. Observing the trend of evening blood pressure decline over time
d. Comparing pre and post intervention heart rate variability measures
e. Comparing pre and post intervention c-reactive protein measures

Pre and post intervention state anxiety scores could not be analyzed because the instruments used (Trait vs State Anxiety) were not comparable. However, using a one-way MANOVA, there was no significant difference [F (2, 62) = .123, p = .884 ($\eta 2$ = .004)] between the Music with BBT group and the Music Only group in regard to their Trait and State Anxiety scores. When using a one-way ANOVA, there was no significant difference in Trait Anxiety [F(1, 63) = .25, p = .621 ($\eta 2$ = .004)] Music Only mean = 40.77; Music with BBT mean = 39.38 nor State Anxiety [F(1, 63) = .015, p = .902 ($\eta 2$ < .001)]; Music Only Mean = 32.74; Music with BBT Mean = 32.47)]. (Figure 1)

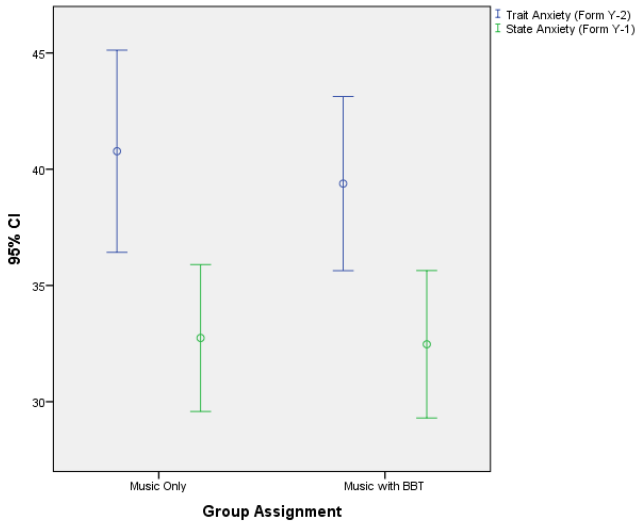
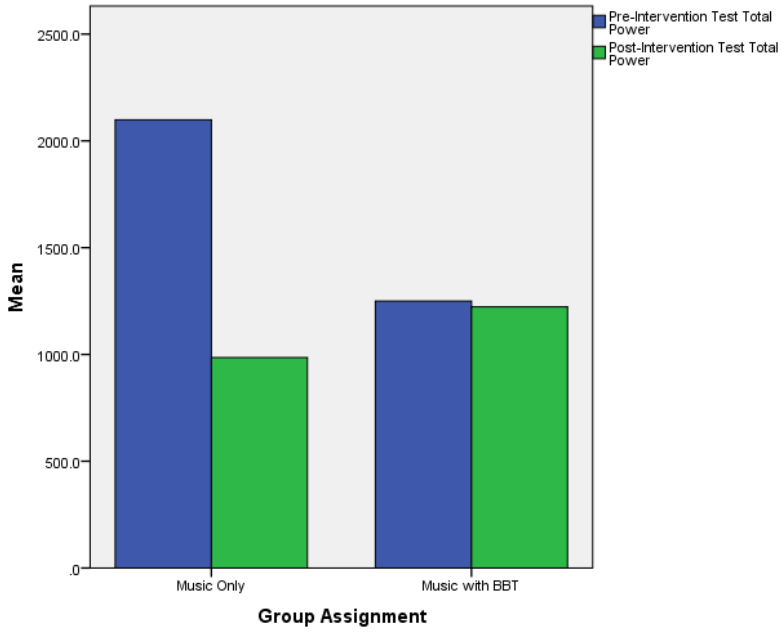


Figure 1. State and Trait Anxiety

Using a 2 x 3 mixed ANOVA (group x time), there was no significant difference [F(2, 104) = 1.42, p = .246 ($\eta 2$ = .027)] in morning systolic blood pressure surge over time, nor in evening systolic blood pressure decline [F(2, 104) = .07, p = .935 ($\eta 2$ = .001)].

Pre and post intervention heart rate variability measures were assessed using five difference variables (heart rate, standard deviation of the normal-to-normal intervals [SDNN], total power,

low frequency, and high frequency) during three phases (before, during, and after a psychological stressor). A significant difference [$F(1, 57) = 4.39$, $p = .041$ ($\eta 2 = .072$)] was found in Total Power measure while under stress, wherein the Music Only group significantly decreased (Pre = 2098.90; Post = 985.26) while the Music with BBT group remained steady (Pre = 1249.75; Post = 1223.07). This suggests that the Music Only group exhibited more signs of chronic stress when placed under stress. A significant difference [$F(1, 63) = 7.56$, $p = .008$ ($\eta 2 = .107$)] was also found in low frequency measures while under stress. Using a 2 x 2 mixed ANOVA, it was found that the Music with BBT group showed a decrease over time (Pre = 77.83, Post = 75.33) whereas the Music Only group showed an increase (Pre = 66.42, Post = 74.41). This suggests that those who used music alone exhibited greater sympathetic response. Finally, a significant difference [$F(1, 63) = 7.56$, $p = .008$ ($\eta 2 = .107$)] was found in high frequency measures while under a stressor. The Music with BBT group showed an increase in mean over time (Pre = 22.17, Post = 24.67), whereas the Music Only group showed a decrease over time (Pre = 33.58, Post = 25.94). This suggests that those who used the technology had greater parasympathetic control while being stressed. (Figure 2)



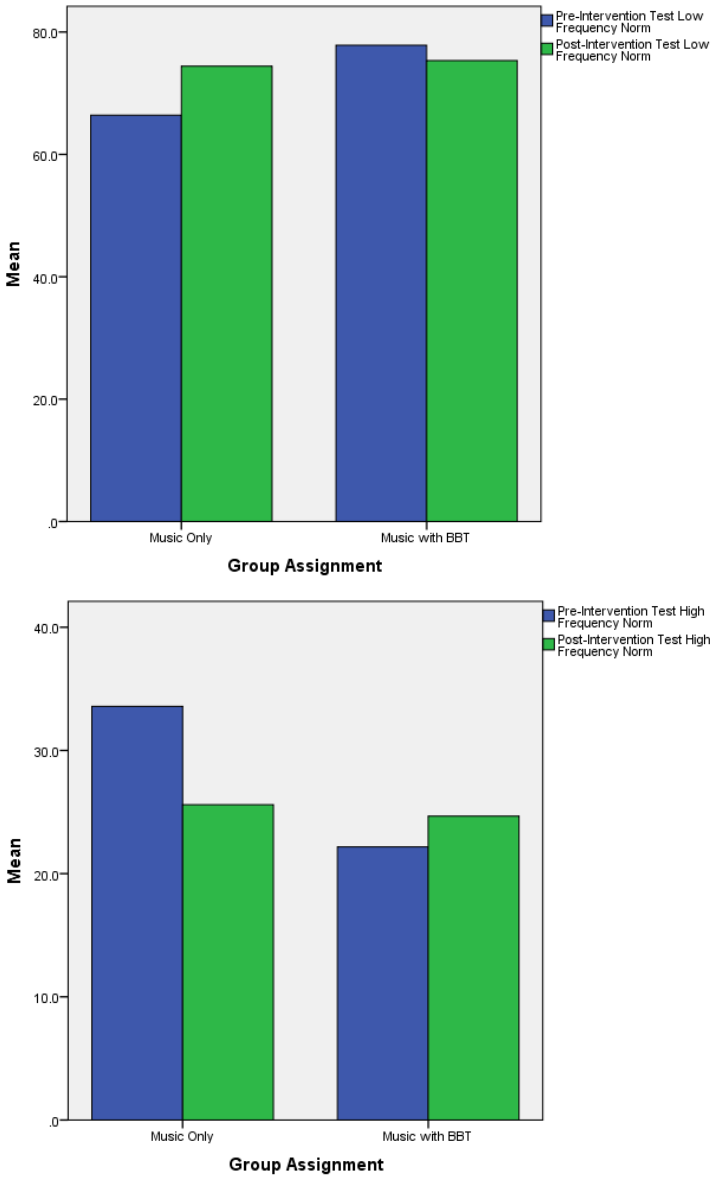


Figure 2. Total Power, Low Frequency, and High Frequency Heart Rate Variability "During a Stressor"

As for c-reactive protein measures, although there was a decrease in the intervention group (Music with BBT Pre = .253; Post = .211 vs Music Only Pre = .148; Post = .233), it was not statistically significant $F(1, 63) = 1.08$, $p = .304$ ($\eta 2 = .017$). (Figure 3)

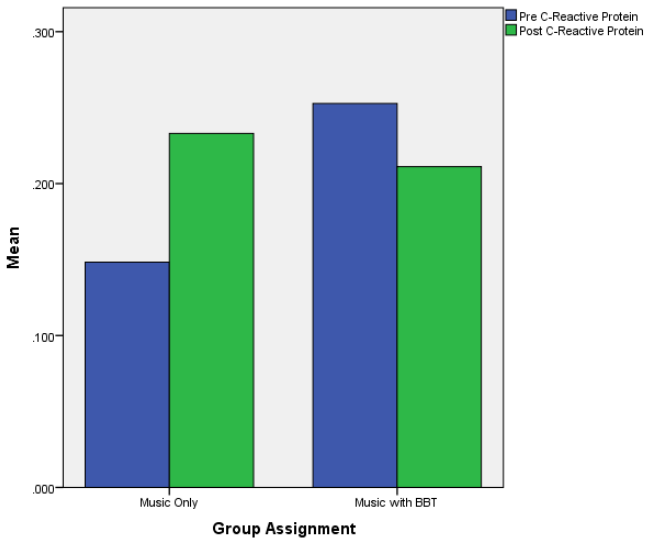


Figure 3. Pre and Post C-Reactive Protein

Aim 2 - To assess the feasibility of implementing a Binaural Beat Technology intervention in a military population during the high-risk post-deployment window by addressing:
a. retention
b. number of refusal during recruitment
c. number of dropouts
d. reason for dropouts
e. reason for staying
f. number of days the technology was used
g. selection of music
h. ease of use and comfort of equipment
i. adherence to the protocol

The study had a 12% attrition rate (n = 9) which was equally distributed between both groups [Music with BBT (n = 5, 13% attrition) and Music Only (n = 4, 11% attrition)]. Twenty-three percent of those contacted (n = 191) refused to participate in the study with 29.7% of the recruitment interest being from the study flyers, followed by 23% from both participant referral and a recruitment table stationed in a high traffic area. (Figure 4)

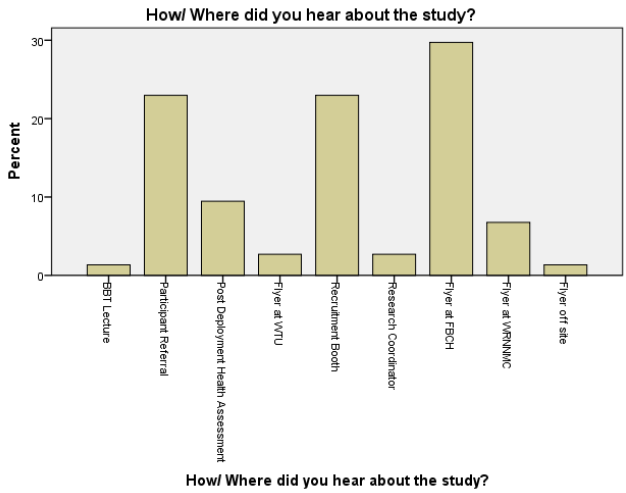


Figure 4. Recruitment Strategies

Based on the 12% attrition, there were six main reasons for withdrawal: no reason given (n = 1), participant was placed on a medication that was an exclusion criterion (n = 2), participant was withdrawn due to non-compliance (n = 1), blood pressure device kept participant awake (n = 1), personal/family issues (n = 3), and participant had bad dreams while using the intervention (n =1).

When asked why participants remained in the study, several participants stated that they were less tensed at work and at home. (Figure 5) When comparing both groups, the Music with BBT group consistently had lower scores across all time points. Anxiety level over the time showed no significant: $F(3, 177) = .123$, $p = .946$ ($\eta 2 = .002$). Music Only (Week 1 = 4.44; Week 2 = 4.42; Week 3 = 4.62; Week 4 = 4.32) vs Music with BBT (Week 1 = 4.29; Week 2 = 4.02; Week 3 = 4.26; Week 4 = 3.96). (Figure 6) When asked to rate their mood, although not significant, the Music with BBT group had higher means across all time points and progressively got better over time, with BBT(Week 1 = 6.33; Week 2 = 6.52; Week 3 = 6.82; Week 4 = 6.88) vs Music Only (Week 1 = 6.27; Week 2 = 6.38; Week 3 = 6.38; Week 4 = 6.13). (Figure 7)

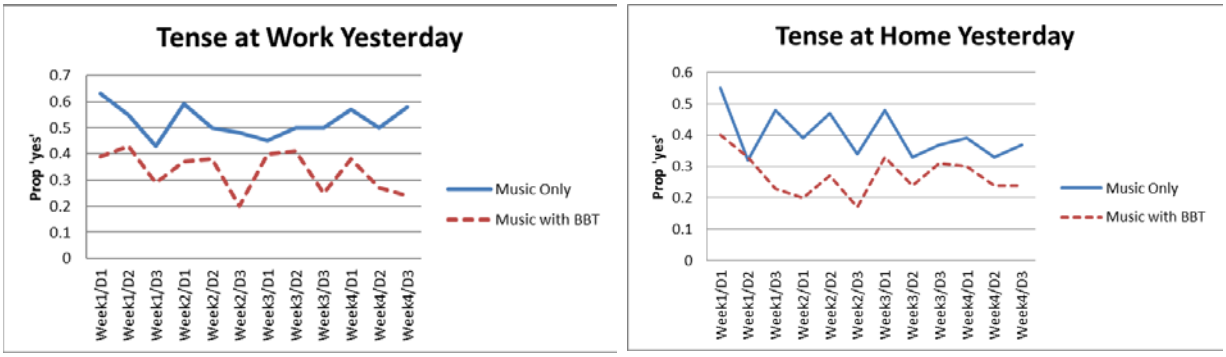


Figure 5. Anxiety at Work and Home

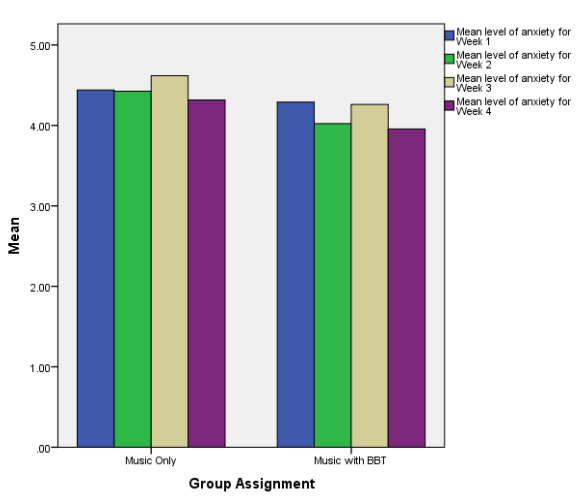


Figure 6. Anxiety Score

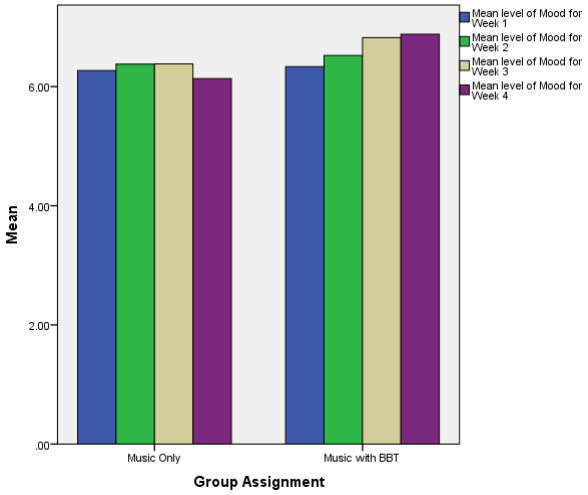


Figure 7. Mood Score

When assessing the quality, comfort, and usability of the equipment used in the study, 49.2% rated the blood pressure devices ‘easy’ to use, 84.5% rated the Sleephones ‘extremely easy’ to use, and 40% rated the MP3 Players ‘extremely easy’. (Figure 8)

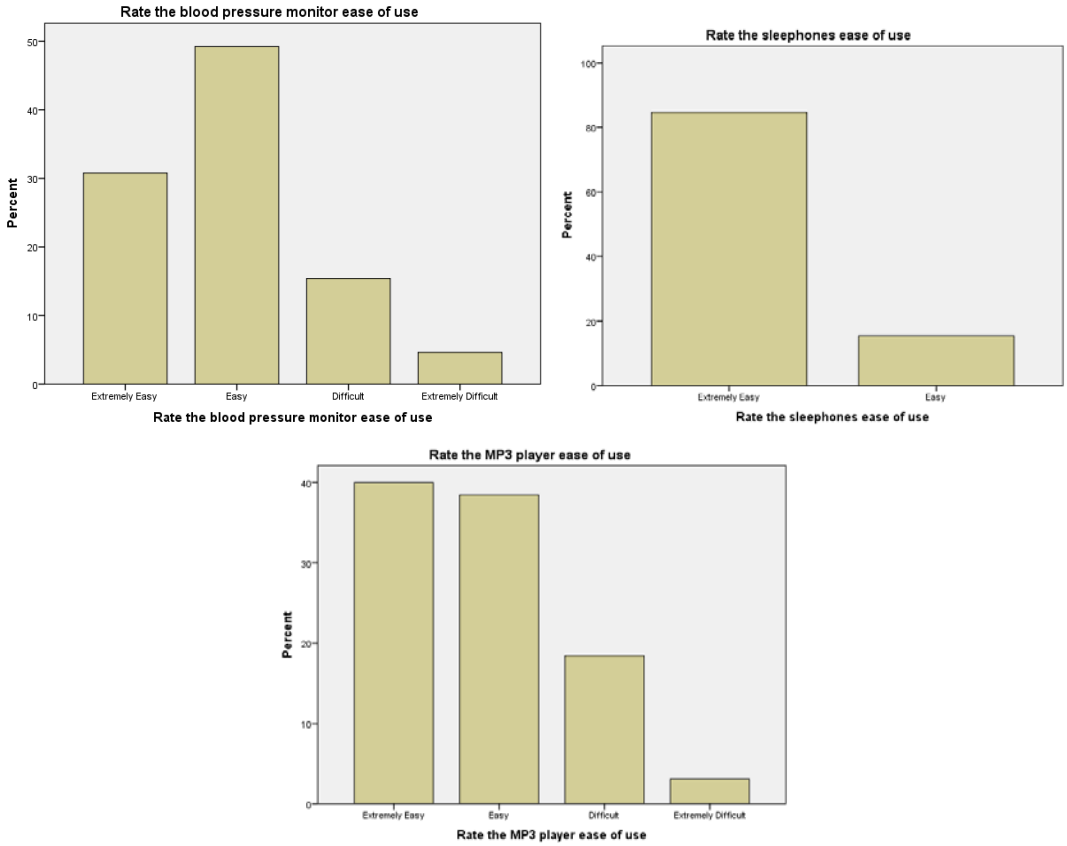


Figure 8. Equipment Ease of Use

As for level of comfort, for the blood pressure device 47.7% rated it ‘not comfortable’ and for the Sleephones 61.5% rated them ‘extremely comfortable’. (Figure 9)

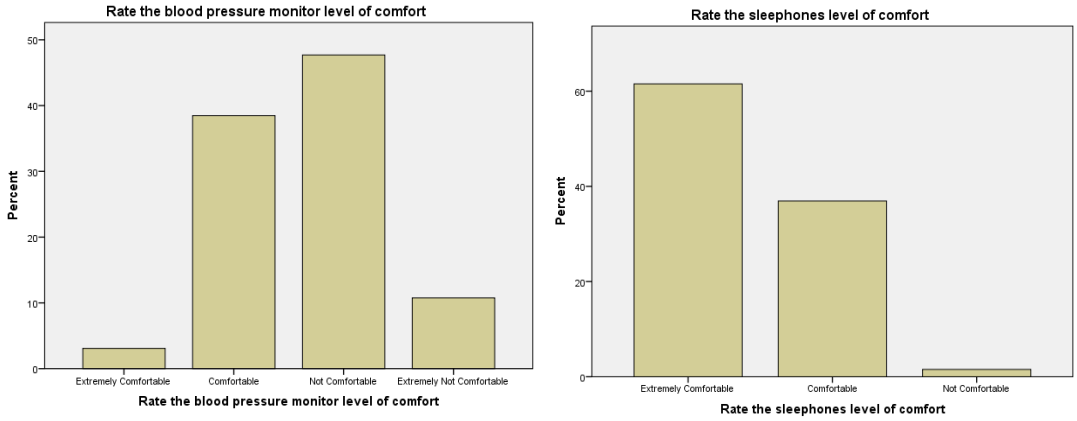


Figure 9. Equipment Level of Comfort

When assessing how often the intervention was used, 20.6% of the Music with BBT group and 16.7% of Music only stated that they used it for 'more than 3 nights per week'. (Figure 10)

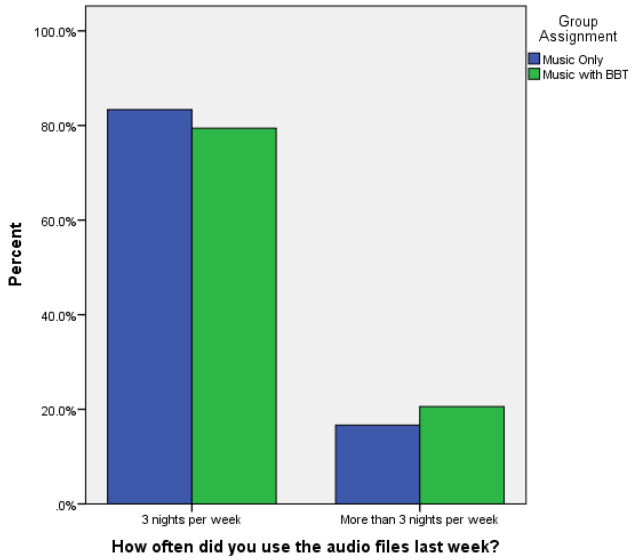


Figure 10. Use of Intervention

As for adherence to protocol, 70% of the Music only group vs 40% of the Music with BBT group used their intervention 100% of the prescribed time whereas 25% of the Music only group vs 60% of the Music with BBT group used their intervention 75% of the prescribed time.

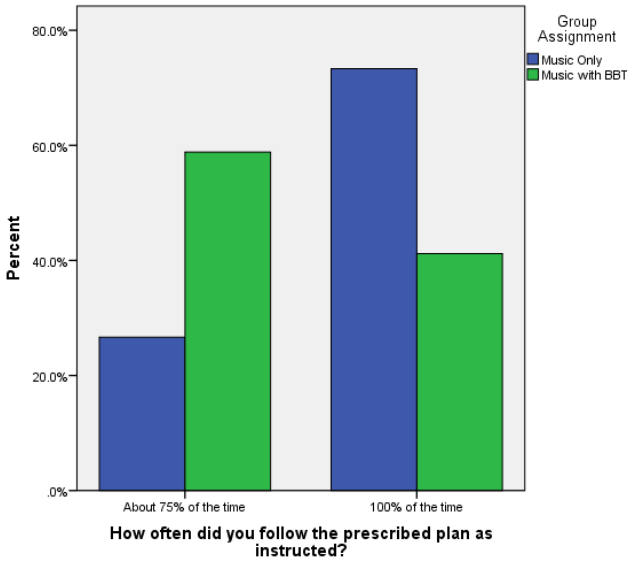


Figure 11. Adherence to Protocol Instructions

Finally, selection of music type could not be determined as the mp3 players were designed in a manner that made it difficult to skip to a desired track.

Relationship of current findings to previous findings: Across the variety of BBT studies that have been conducted findings have been mixed, which is why replication studies are important. When assessing the effect of BBT on HRV, there was only one other documented study (McConnell, 2014). Using a slightly similar design and BBT in the same theta brainwave frequency, efficacy was assessed using a "physical" stressor, whereas this study used a "psychological" stressor. Findings were similar, showing a greater self-report of relaxation with increased parasympathetic activation and decreased sympathetic response after using the technology. However, in the McConnell study, BBT was used in one increment with the effect diminishing at the 20-minute mark, whereas in this study when the BBT was used consistently over several weeks, it showed the effect progressively improving over time (Figure 7).

Effect of problems or obstacles on the results: Overall, this study had very few problems or obstacles. First, there was the inability to objectively track the total number of minutes that the technology was used over the course of the four weeks. If the mp3 player had a time tracker, this would have been beneficial. Second, missing diary entries were the biggest contributing factor to incomplete data.

Limitations: This study had several limitations. First, the two groups were not divided equally (e.g., 37 vs 37). When the distributor of the technology was asked to make the groups equally distributed, they inadvertently sent two equal groups instead (36 vs 38). Since the study was double blinded, the investigator was not aware of this until the end. Although not divided equally, this did not make a significant impact on the results. Second, even with randomization, more females were in the control group than the intervention group (39% vs 18%). Also, given that it is common to have more males versus females in military studies, a gender difference analysis could not be conducted. Third, other than verbal confirmation from the participants and entries in their daily diaries, there was no way to objectively capture the total number of minutes

that the intervention was used. Fourth, daily diary input was inconsistent for both groups over the course of the four weeks. Finally, due to the design of the mp3 player, participants did not have the ability to select music type so music preference could not be analyzed.

Conclusion: When assessing the effect of music with BBT compared to music alone, findings showed that those who used BBT had lower anxiety and better mood when compared to those who used music alone. When assessing pre and post heart rate variability findings, both groups showed a decline in Total Power HRV measures; however, the decline was more substantial in the music only group. In other words, those who did not use music with BBT showed more clinical signs of chronic stress when placed under a mental stressor. When comparing pre and post HRV low and high frequencies, those who used BBT had a decrease in low frequency and an increase in high frequency, whereas those who used music only had the opposite effect. In other words, when stressed, those who used BBT had a decreased sympathetic response and an increase in parasympathetic control, while those with music only had the opposite effect.

As for the feasibility of using BBT in the post deployment population, those who used BBT had a steady increase in compliance over time, whereas those who used music only remained steady, with both groups dropping in compliance at week 4. As for ease and use of equipment, the majority of the participants responded favorably for the SleepPhones and the level of quality of the audio file from the distributor. However, better mp3 players are needed for future studies. Even though 50% of the participants were in the control group, 80% of the entire sample stated that they would consider using BBT in other brainwave frequencies if available and would recommend BBT to family, friends, and coworkers. Finally, the only deterrents for using the technology as prescribed were equipment failure/user error.

Significance of Study or Project Results to Military Nursing

The use of programs and products from the Monroe Institute (the distributer of this technology) is not new to the military. In the late 1970s through the early 80s, the U.S. Army developed the "Star Gate" program, honing the ability to get into deep meditative states to "remote view" areas of interest for military intelligence. Program administrators collaborated with the Monroe Institute in RAPT (Rapid Acquisition Personnel Training) and INSCOM (Intelligence & Security Command). During that time, an Army psychologist organized a project at Fort Benjamin Harrison to see if the institute's technology would enhance learning abilities (Waldkoetter & Milligan, 1978, Waldkoetter, 1983, and Waldkoetter & Vandivier, 1992). Since then, the program has been terminated, but advancements in using the institute's principles and technology in the military continues, as evidenced by their new "Attention/At Ease" product (Monroe Institute, 2016). However, more studies need to be conducted within the military community in a variety of military relevant settings.

Although not approved or monitored by the Food and Drug Administration, the technology is available to the general public and has shown success in a variety of studies. This study showed that using the technology over time did in fact have a positive effect on the CV stress response, as well as one's level of perceived stress. The study also showed that it is feasible to use in the military community and that service members are interested in exploring its efficacy in other brainwave frequencies (e.g. delta frequency for better sleep quality, beta frequency for attention and focus, etc.). In military healthcare, the technology would not require a doctor's order, nor does it need to be administered by an advanced practice provider. It can be an independent nurse initiated action initiated as a complementary and alternative option for the management of stress, not only for the patient but for the nurse as well. This technology is flexible, as it can be used at the bedside, in an outpatient setting, at home, and even on military deployments. Finally, given the stigma often associated with post deployment stress, the use of the technology is unassuming, as it appears as though the service member is simply listening to music.

Changes in Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine that Resulted from Study or Project

Clinicians, especially those in the mental health community, should be educated regarding the technology, its uses, and effect. Since the technology is marketed to the general public through venues such as YouTube, Apple App store, and Apple iTunes and is not FDA regulated, there is no guarantee that proper quality control measures were put in place. There is no way to validate that the proper brainwave frequency was embedded or if it was embedded at all. Knowing this, clinicians should be aware that their patients may be using the technology and not divulging it during their clinical intake or health assessments. As for clinical researchers who plan to conduct BBT research in the military, they need to be cautious when attempting to use the technology in a post deployed population, given that many may have sustained mild to moderate traumatic brain injuries (TBI). The sound technology may in fact worsen the ringing in the ears, which is one of the most common clinical presentations, and it is unclear if the manipulation of brainwave activity may worsen the clinical presentations of a TBI.

Since this was the first study using this technology in a military population, more military relevant studies need to be conducted before determining if its use warrants policy changes. Just as once accepted over the counter supplements are now banned from the military, diligence in assessing patients' usage as well as more rigorous studies (e.g. with the use of functional magnetic resonance imaging) are essential.

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Waldkoetter, R. O., & Vandivier, P. L. (1992). Auditory guidance in officer level training. Paper presented at the 34th Annual Conference of the Military Testing Association, San Diego CA.

Waldkoetter, R. O. (1983). The use of audio-guided stress reduction to enhance performance. Paper presented at the 25th Annual Conference of the Military Testing Association, Gulf Shores AL.

Waldkoetter, R. O;, & Milligan, J. R. A Learning-Receptive State as Induced by an Auditory Signal or Frequency Pulse. Paper presented at the 20th Annual Conference of the Military Testing Association, Oklahoma City, OK, 1978. No PMCID number

Summary of Dissemination

Type of Dissemination	Citation	Date and Source of Approval for Public Release
Publications	None (see below)	
Publications in Press	None	
Published Abstracts	Gantt, M. (2016). Binaural beat technology: Can an auditory neurophysiologic technique positively affect the cardiovascular stress response? *Journal of Traditional Medicine & Clinical Naturopathy* *5*(2) Supp., 27	Jan 2016 Source: Regional Health Command Europe Public Affairs Office
Podium Presentations	Gantt, M. The Sound Mind Warrior Study: Using Sound Technology to Combat Stress in Military Service Members. Sigma Theta Tau International 27th International Nursing Research Congress, Cape Town, South Africa; 27 July 2016 Gantt, M ."Binaural beat technology: Can an auditory neurophysiologic technique positively affect the cardiovascular stress response? 6th International Conference and Exhibition on Traditional and Alternative Medicine. Amsterdam, Netherlands; 14 September 2016	Jan 2016 Source: Regional Health Command Europe Public Affairs Office Jan 2016 Source: Regional Health Command Europe Public Affairs Office
Poster Presentations	Gantt, M. Binaural beat technology: Can it really affect the cardiovascular stress response? 2016 Royal College of Nursing International Nursing Research Conference; Edinburgh, Scotland, 7 April 2016.	Jan 2016 Source: Regional Health Command Europe Public Affairs Office
Media Reports	University of Central Florida Alumni Professional Achievement Award Video http://www.youtube.com/watch?v=xX9IsP6U23M&list=FLb8HRnW9wyJcZSbazHCE2RA&index=7 Army Nurse Corps Newsletter (December 2012) http://armynursecorps.amedd.army.mil/newsletter.html	25 Jul 2012 Source: Fort Belvoir Community Hospital Public Affairs Office 01 Dec 2012 Source Army Nurse Corps

	Fort Belvoir Community Hospital Headline News http://www.fbch.capmed.mil/newsroom/20140604_01.aspx	04 Jun 2014 Source: Fort Belvoir Community Hospital Public Affairs Office
Other	Gantt, M., The Sound Mind Warrior Study: Overview of study finding presented at the 2015 annual team meeting, Fort Belvoir, Virginia 06 Jul 2015.	N/A

*** Publications in Review:**

There is currently one manuscript under review by the Journal of Nursing Scholarship:
Gantt, M., Dadds, S., Burns, D. & Moore, A. (2016). The effect of binaural beat technology on the cardiovascular stress response in military service members with post deployment stress.

Reportable Outcomes

Reportable Outcome	Detailed Description
Applied for Patent	None
Issued a Patent	None
Developed a cell line	None
Developed a tissue or serum repository	None
Developed a data registry	None

Recruitment and Retention Table

Recruitment and Retention Aspect	Number	
Subjects Projected in Grant Application	74	
Subjects Available	Unknown	
Subjects Contacted or Reached by Approved Recruitment Method	191	
Subjects Screened	191	
Subjects Ineligible	74	
Subjects Refused	43	
Human Subjects Consented	74	
Subjects Intervention Group / Control or Sham Group	38	36
Intervention Group / Control or Sham Group Subjects Who Withdrew	5*	4*
Intervention Group / Control or Sham Group Subjects Who Completed Study	33	32
Intervention Group / Control or Sham Group Subjects With Complete Data	18	15
Intervention Group / Control or Sham Group Subjects With Incomplete Data	15	17

* Reason for leaving study: No reason given (n = 1), Placed on a medication that was an exclusion criteria (n = 2), Withdrawn by PI due to non-compliance (n = 1), BP cuff kept participant awake (n = 1), Personal/family issues (n = 3), and Had bad dreams while using the technology (n = 1).

Demographic Characteristics of the Sample

Demographics		**Music with BBT n = 37 (51%)[1]**	**Music only n= 36 (49%)**	***p*-value**
Age (yrs.) mean (SD)		38.3 (±8.29)	37.9 (±10.16)	0.873
Race	American Indian or Alaskan Native	1 (3%)	0 (0)	0.423
	Asian	3 (8%)	4 (11%)	
	African American	11 (30%)	5 (14%)	
	Caucasian	21 (57%)	24 (69%)	
	Other	1 (3%)	2 (6%)	
Ethnicity	Non-Hispanic	11 (65%)	12 (8%)	0.52
	Hispanic	6 (35%)	4 (25%)	
Gender	Female	7 (18%)	14 (39%)	0.051
	Male	31 (82%)	22 (61%)	
Marital Status	Single	8 (22%)	9 (25%)	0.727
	Separated	2 (5%)	4 (11%)	
	Divorced	5 (14%)	3 (8%)	
	Married	22 (60%)	20 (56%)	
Branch	Army	26 (70%)	25 (69%)	0.811
	Navy	6 (16%)	8 (22%)	
	Air Force	4 (11%)	2 (6%)	
	Marines	1 (3%)	1 (3%)	
Military Status	Active Duty	32 (84%)	32 (89%)	0.893
	Reserve	2 (5%)	2 (5%)	
	National Guard	2 (5%)	1 (3%)	
	Retired	2 (5%)	1 (3%)	
Months Deployed mean (SD)		9.84 (5.29)	9.67 (3.68)	0.87
Times Deployed mean (SD)		2.32 (1.42)	2.89 (3.79)	0.387

[1]Sample sizes may differ given missing data.